reasonable cost. The objectives of competitive bidding include:

(1) To implement competitive bidding programs for certain covered items of DMEPOS and associated services in select areas;

(2) to assure beneficiary access to quality DMEPOS as a result of the program;

(3) to reduce the amount Medicare pays for DMEPOS and create a payment structure under competitive bidding that is more reflective of a competitive market;

(4) to limit the financial burden on beneficiaries by reducing their out-of-pocket expenses for DMEPOS they obtain through the program; and,

(5) to contract with suppliers who conduct business in a manner that is beneficial for the program and Medicare beneficiaries.

Contract suppliers will be selected from the suppliers that have the lowest bids and that meet all relevant program requirements. Suppliers bidding above the winning price are to be excluded from the Medicare market; however, multiple winners must be awarded in each site. The forms associated with this collection of information will collect all of the relevant information needed for processing bids.

Following the publication of the 60-day **Federal Register** notice (71 FR 26546), we received a considerable number of public comments. Commenters discussed a variety of topics, ranging from the general requirements of the forms to the availability of instructions for completing the forms. After reviewing the comments, we revised the information collection request (ICR) to clarify the issues raised by the public. In addition, instructions for completing the forms are complete and available for public viewing. *Form Number:* CMS–10169 (OMB#: 0938–NEW); *Frequency:* Reporting—Every three years; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and the Federal government; *Number of Respondents:* 23,973; *Total Annual Responses:* 23,973; *Total Annual Hours:* 1,088,164.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Written comments and recommendations for the proposed information collections must be mailed or faxed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, *Attention:* Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: December 7, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–21436 Filed 12–14–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0037]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Proposed Experimental Study of Trans Fat Claims on Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 16, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Proposed Experimental Study of *Trans* Fat Claims on Foods—(OMB Control Number 0910–0533—Reinstatement)

FDA is requesting OMB approval of a proposed experimental study of trans fat claims on food products intended to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for *trans* fat claims on foods.

In the **Federal Register** of July 11, 2003 (68 FR 41507), FDA issued an advance notice of proposed rulemaking entitled ''Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements,'' which requested comments about possible disclosure requirements to accompany nutrient content claims about *trans* fatty acids that could help consumers make heart-healthy food choices. The proposed experimental study will evaluate the ability of several such disclosure requirements to help consumers make heart-healthy food choices. The results of the proposed experimental study will provide empirical support for possible policy decisions about the need for such disclosures and the appropriate form they should take.

FDA or its contractor will collect and use information gathered from Internet panel samples to evaluate how consumers understand and respond to possible disclosure requirements for *trans* fat content claims. The distinctive features of Internet panel and shopping mall methodologies for the purpose of the proposed experimental study are that they allow for controlled visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. Experimental manipulation of labels and random assignment to condition makes it possible to estimate the effects of the various possible disclosure requirements while controlling for individual differences. Random assignment ensures that mean differences between conditions can be tested using well-known techniques such as analysis of variance or regression analysis to yield statistically valid estimates of treatment effect size. The proposed study will be conducted with a convenience sample drawn from a large, national consumer panel with about one million households.

Participants will be adults, age 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to 1 of the 144 experimental conditions consisting of fully crossing 8 disclosure conditions, 3 product types, 3 fatty acid profiles and 2 prior knowledge conditions.

FDA will use the information from the proposed experimental study to evaluate regulatory policy options. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from this proposed experimental study will be used by the agency to assess likely consumer responses to various disclosure requirements for nutrient content claims.

In the **Federal Register** of February 6, 2006 (71 FR 6076), FDA published a 60–day notice requesting public comment on the information collection that will take place as part of the experimental study. FDA received one letter in response to the notice, containing multiple comments.

(*Comment 1*) One comment stated that the organization concurs with the objectives of the study and believes the information from this study will be useful to FDA in developing labeling policy to assist consumers with interpretation of *trans* fat claims in food labeling. Another comment suggested that FDA change the labels used to describe the three fatty acid profiles in the study (''good profile,'' ''medium profile,'' and ''poor profile'') because these descriptors were seen as overly negative. The comment recommended alternative language (''low profile,'' ''medium profile'' and ''high profile'') as a way to ensure that the products are not characterized as ''good foods'' or ''bad foods.''

(*Response*) This suggestion has been implemented. The terminology suggested in the comment adequately conveys the intended profile differences.

(*Comment 2*) One comment critiqued the draft Full Information treatment language. The comment criticized the one-page summary because it : (1) Did not identify calories in the discussion of fat as a major source of energy and (2) did not relate the calorie contribution of fat to that of carbohydrates and protein. The comment also criticized the information about sources of *trans* fat because it omitted mention of natural sources of *trans* fat in the diet, which the comment suggested would help ensure factually correct and balanced information about sources of *trans* in the diet. The comment questioned the value of stating that *trans* fat extends shelflife and has desirable taste characteristics since many saturated fat sources are relatively shelf stable and have desirable taste characteristics.

(*Response*) FDA agrees and has revised the Full Information treatment to incorporate these concerns. Calories and other sources of energy are now mentioned in the introductory passage. Natural sources of *trans* fat are now mentioned and the similarity between *trans* fat and saturated fat in terms of shelflife and taste are now addressed. The revised draft will be included in the study pretest and further revisions will be made if FDA determines they are needed based upon pretest results.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	40	1	40	.25	10
Study	2,880	1	2,880	.25	720
Total					730

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 8, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–21317 Filed 12–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0197]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 16, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.230 through 1.235 (OMB Control Number 0910–0502)—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 415 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350d), which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. Sections 1.230 through 1.235 (21 CFR 1.230 through 1.235) set forth the procedures for registration of food facilities. Information provided to FDA under these regulations will help the agency to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply.

Description of respondents: The respondents to this information collection include owners, operators, or